22177. Misbranding of B. & M. & B. & M. External Remedy. U. S. v. F. E. Rollins Co. Plea of guilty. Fine, $2,000. (F. & D. no. 30186. I. S. nos. 30359, 30439, 30728. Sample nos. 2650–A, 2674–A, 4081–A, 4463–A, 4464–A, 5885–A, 6127–A, 6321–A, 6323–A, 6876–A, 6877–A, 6878–A, 6879–A, 6880–A, 6881–A, 7371–A, 7372–A, 7719–A, 9330–A, 9331–A, 9332–A, 18177–A.)

This case was based on interstate shipments of a drug preparation under two types of labeling, the earlier shipments under the name of B. & M. External Remedy and the later shipments under the name of B. & M. Analyses showed the same formula under both types of labeling. The carton and bottle labels and booklets shipped with the article contained false and fraudulent curative and therapeutic claims.

On February 12, 1934, the United States attorney for the District of Massachusetts, acting upon a report by the Secretary of Agriculture, filed in the district court an information against the F. E. Rollins Co., a corporation, Boston, Mass. It was alleged in the information that the defendant company had shipped from the State of Massachusetts into the States of Pennsylvania, New York, and Alabama, between the dates of May 9, 1931, and April 28, 1932, quantities of B. & M. External Remedy; that the said company had also shipped from the State of Massachusetts into the States of Louisiana, Florida, Minnesota, Illinois, Rhode Island, Michigan, Ohio, and Missouri, between the dates of April 30, 1932, and July 14, 1932, quantities of B. & M.; and that the article was misbranded in violation of the Food and Drugs Act as amended. The shipments labeled "B. & M." were further labeled in part: "Formerly Called B. & M. External Remedy."

Analyses of samples of the article by this Department showed that it consisted essentially of approximately 42 percent of turpentine oil, approximately 5 percent of ammonia, small proportions of ammonium salicylate, hexamethylenamina, thiosinamine, and a phenolic substance such as cresol, albuminous and phosphorus-containing material such as egg, and water.

The information charged that the article was misbranded in that the cartons, bottle labels, and booklets within the cartons contained statements, designs, and devices representing that the article contained ingredients capable of exerting curative and therapeutic effects in the treatment of various ailments, namely, that the portions labeled "B. & M." were effective in the treatment of pulmonary tuberculosis, tuberculosis of the cervical glands, tuberculosis of the joints, tuberculosis of other parts of the body, pneumonia, influenza, laryngitis, bronchitis, croup, coughs, tonsilitis, rheumatism, inflammatory rheumatism, lumbago, neuritis, septic skin infections, sciatica pleurisy germ diseases, hemolytic streptococcus infections, mixed infections, and blood poisoning, and that the portions labeled "B. & M. External Remedy" were effective in the treatment of pulmonary tuberculosis, tuberculosis of the cervical glands, tuberculosis of the joints, tuberculosis of other parts of the body, pneumonia, la grippe, bronchitis, pleurisy, influenza, catarrh, acute and chronic rheumatism, inflammatory rheumatism, rheumatic fever, blood poisoning, inflammation of the bowels, tonsilitis, lumbago, neuritis, neurasthenia, peritonitis, scarlet fever, diphtheria, whooping cough, croup, mumps, auto-intoxication, kidney trouble, bladder trouble, poliomyelitis or infantile paralysis, indigestion, varicose veins, and all kinds of inflammation, whereas the article contained no ingredients or combination of ingredients capable of producing the effects claimed and the statements were applied knowingly, fraudulently, and in reckless and wanton disregard of their truth or falsity.

On March 5, 1934, a plea of guilty was entered on behalf of the defendant company, and the court imposed a fine of $2,000.

M. L. WILSON, *Acting Secretary of Agriculture.*

22178. Misbranding of Osmo Kaolin. U. S. v. E. Fougera & Co., Inc. Plea of guilty. Fine, $375. (F. & D. no. 26628. I. S. nos. 5717, 5738, 5742.)

This case was based on shipments of Osmo Kaolin, a product labeled with therapeutic claims, which was found upon analysis to consist entirely of clay. The article contained no ingredient, nor was it in itself, capable of producing certain therapeutic and curative effects claimed in the labeling.

On October 11, 1932, the United States attorney for the Southern District of New York, acting upon a report by the Secretary of Agriculture, filed in the district court an information against E. Fougera & Co., Inc., a corporation, New York, N. Y., alleging shipments by said company in violation of the Food and Drugs Act, as amended, on or about December 6, 1929, November 19 and December 12, 1930, from the State of New York into the Territory of Puerto

Rico, of quantities of Osmo Kaolin which was misbranded. The article was labeled in part: (Box) "'Osmo' Kaolin (Morson) A Pure, Sterile Colloidal Kaolin * * * U. S. Agents—E. Fougera & Co., Inc., * * * New York, N. Y."

Analyses of samples of the article by this Department showed that it consisted of a fine, soft clay containing no organic material nor any mineral salts.

It was alleged in the information that the article was misbranded in that certain statements, designs, and devices appearing on the label falsely and fraudulently represented that it was effective as an invaluable treatment of disorders arising from intestinal infection by bacteria; effective to absorb the toxins arising from intestinal infection; effective to eliminate the toxins arising from intestinal infection readily, quickly, and safely, without harm to the system; effective as a treatment, remedy, and cure for dysentery, cholera, diarrhoea, ulcerative colitis, rheumatism, gout and intestinal stasis; effective when employed in the preparation of cataplasmata to remove oedema, relieve pain and swelling of local inflammation; and effective to absorb irritant discharges.

On April 4, 1934, a plea of guilty was entered on behalf of the defendant company, and the court imposed a fine of $375.

M. L. WILSON, *Acting Secretary of Agriculture.*

22179. Adulteration and misbranding of citrate of magnesia. U. S. v. Druggist Magnesia Corporation, Bernard Kleinschmidt, Louis Kleinschmidt, William Wohlers, and Max Frei. Pleas of guilty. Fines, $150 imposed on each count against each defendant. Louis Kleinschmidt and Bernard Kleinschmidt paid $450 each. Remaining fines suspended. (F. & D. no. 27520. I. S. nos. 20121, 38162, 38733.)

This case was based on shipments of citrate of magnesia which was deficient in acidity and total citric acid. Sample bottles taken from each of the shipments were found to contain less than the declared volume.

On February 8, 1934, the United States attorney for the Southern District of New York, acting upon a report by the Secretary of Agriculture, filed in the district court an information against the Druggist Magnesia Corporation, and Bernard Kleinschmidt, Louis Kleinschmidt, William Wohlers, and Max Frei, proprietors of the said corporation, alleging shipment by said defendants, on or about February 13, July 17, and October 16, 1931, from the State of New York into the State of Connecticut, of quantities of citrate of magnesia which was adulterated and misbranded. Portions of the article were labeled in part: (Blown in bottle) "Solution Citrate Magnesia"; (bottle cap) "Citrate of Magnesia U. S. P. Contents 11½ Fluid Oz." The remainder was labeled in part: (Blown in bottle) "Citrate of Magnesia Solution Citrate Magnesia"; (bottle cap) "D Contents 11½ Fluid Ounces U. S. P. X."

It was alleged in the information that the article was adulterated in that it was sold under a name recognized in the United States Pharmacopoeia, and differed from the standard of strength, quality, and purity as determined by the test laid down in said pharmacopoeia official at the time of investigation, in that it required less than 9.5 cubic centimeters (8.4 cc, 8.09 cc, and 8.37 cc, respectively) of half-normal sodium hydroxide for neutralization of the acid in 10 cubic centimeters of the article, and less than 28 cubic centimeters (25 cc, 25.95 cc, and 26.89 cc, respectively) of half-normal sulphuric acid for neutralization of the ash of 10 cubic centimeters of the article, whereas the pharmacopoeia provides that 10 cubic centimeters of solution of magnesium citrate, to wit, citrate of magnesia, shall require not less than 9.5 cubic centimeters of half-normal sodium hydroxide for neutralization of the acid, and that 10 cubic centimeters shall require not less than 28 cubic centimeters of half-normal sulphuric acid for neutralization of the ash; and the standard of strength, quality, and purity of the article was not declared on the container.

Misbranding was alleged for the reason that the statements, "Solution Citrate of Magnesia", "Citrate of Magnesia U. S. P." with respect to portions of the article, and "Citrate of Magnesia, Solution Citrate Magnesia", with respect to the remainder and the statement, "Contents 11½ Fluid Ounces", with respect to all lots, were false and misleading, since the article was not citrate of magnesia which conformed to the tests laid down in the United States Pharmacopoeia and the bottles contained less than 11½ fluid ounces of the article.

On February 13, 1934, the Druggist Magnesia Corporation, Louis Kleinschmidt, and William Wohlers entered pleas of guilty, and were each sentenced